Leave Blank
PROPOSAL # ____________
CONDITIONAL APPROVAL DATE ____________
APPROVAL DATE ____________
EXPIRATION DATE ____________

NATIONAL INSTITUTES OF HEALTH

ANIMAL STUDY PROPOSAL

A. ADMINISTRATIVE DATA:

Institute, Center, or Division: ____________ Division, Laboratory, or Branch: ____________

Principal Investigator: ____________

Building: ________ Room: ________ Telephone: ________ FAX: ________

Project Title: ____________

____

Submission: ○ Initial ○ Renewal ○ Modification of Proposal Number ________ List the names of all individuals authorized to conduct procedures involving animals under this proposal and identify key personnel (i.e. Co-investigators(s)):

Name: ____________ Degree: ______ Position Title, Affiliation: ____________
○ Fully qualified in all relevant animal procedures ○ Will be trained and supervised by ____________

Name: ____________ Degree: ______ Position Title, Affiliation: ____________
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B. ANIMAL REQUIREMENTS:

Species: ____________ Age/Weight/Size: ____________ Sex: ______

Stock or Strain: ____________ Source(s): ____________

Holding Location(s): ____________ Animal Procedure Location(s): ____________

Number of Animals To Be Used: ______ + ______ = ______
Year 1 Year 2 TOTAL

C. TRANSPORTATION: Transportation of animals must conform to all NIH and Facility guidelines/policies. If animals will be transported between facilities, describe the methods and containment to be utilized. If animals will be transported within the Clinical Center, also include the route and elevator to be utilized.

D. STUDY OBJECTIVES: Briefly explain in non-technical terms the aim of the study and why the study is important.

E. RATIONALE FOR USE OF ANIMALS: 1) Explain your rationale for animal use. 2) Justify the appropriateness of the species selected. 3) Justify the number of animals to be used.

F. DESCRIPTION OF EXPERIMENTAL DESIGN AND ANIMAL PROCEDURES: Briefly explain the experimental design and specify all animal procedures. This description should allow the ACUC to understand the experimental course of an animal from its entry into the experiment to the endpoint of the study. Specifically address the following:

- Injections or inoculations (substances, e.g., infectious agents, adjuvants, etc.; dose, sites, volume, route, and schedules)
- Blood withdrawals (volume, frequency, withdrawal sites, and methodology)
- Non-survival surgical procedures (Provide details of survival surgical procedures in Section G.)
- Radiation (dosage and schedule)
- Methods of restraint (e.g., restraint chairs, collars, vests, harnesses, slings, etc.)
- Animal identification methods (e.g., earpunches/notches, ear tags, tattoos, collar, cage card, etc.) and other procedures (e.g., survival studies, tail amputations, etc.)
- Resultant effects, if any, the animals are expected to experience (e.g., pain or discomfort, ascites production, etc.)
- Experimental endpoint criteria (i.e., tumor size, percentage body weight gain or loss, inability to eat or drink, behavioral abnormalities, clinical symptomatology, or signs of toxicity) must be specified when the administration of tumor cells, biologics, infectious agents, radiation or toxic chemicals are expected to cause significant symptomatology or are potentially lethal.

G. SURVIVAL SURGERY: If proposed, complete the following:

1. Identify and describe the surgical procedure(s) to be performed. Include the aseptic methods to be utilized.

2. Who will perform surgery and what are their qualifications and/or experience?

3. Where will surgery be performed? Building _____ Room _____

4. Describe post-operative care required and identify the responsible individual.

5. Has major surgery been performed on any animal prior to being placed on this study? Y/N ____ If yes, please explain.

6. Will more than one major survival surgery be performed on an animal while on this study? Y/N ____If yes, please justify.

H. PAIN OR DISTRESS CATEGORY: (See Attachment I for definitions and guidelines.) Indicate the number of animals used each year in each category. Sum(s) should equal total from Section B.

		Year 1	Year 2
USDA Column C	- Minimal, Transient, or No Pain or Distress	_____	_____
USDA Column D	- Pain or Distress Relieved by Appropriate Measures	_____	_____
USDA Column E	- Unrelieved Pain or Distress***	_____	_____

*** If animals are indicated in Column E, a scientific justification is required to explain why the use of anesthetics, sedatives or tranquilizers during and/or following painful or distressful procedures is contraindicated. Please complete the explanation for Column E listings in the continuation of this Section.

I. ANESTHESIA, ANALGESIA, TRANQUILIZATION: For animals indicated in Section H, Column D, specify the anesthetics, analgesics, sedatives or tranquilizers that are to be used. Include name of the agent(s), the dosage route and frequency of administration.

J. METHOD OF EUTHANASIA OR DISPOSITION OF ANIMALS AT END OF STUDY: 1) Indicate the proposed method, and if a chemical agent is used, specify the dosage and route of administration. If methods of euthanasia include those not recommended by the AVMA Panel on Euthanasia (e.g., decapitation or cervical dislocation without anesthesia) justify why such methods must be used. 2) Indicate the method of carcass disposal.

K. HAZARDOUS AGENTS: Use of hazardous agents requires the approval of an ICD safety specialist. Registration Documents are required to be attached for the use of recombinant DNA, human pathogens, or radioisotopes. If controlled substances are used, the controlled substance officer for the laboratory must sign concurrences (Section O).

LIST AGENTS AND REGISTRATION DOCUMENT NUMBER
(Write NONE if not applicable)

1. Radioisotopes _____

2. Biological Agents _____

3. Hazardous Chemicals or Drugs _____

4. Recombinant DNA _____

Study Conducted at Biosafety Level: _____

Describe the practices and procedures required for the safe handling and disposal of contaminated animals and material associated with this study. Also describe methods for removal of radioactive waste and monitoring of the area.

Describe any additional safety considerations.

L. BIOLOGICAL MATERIAL/ANIMAL PRODUCTS: (e.g., cell lines, antiserum, etc.)

1. Specify Material: _____

2. Source: _____ Material Sterile or Attenuated? Y/N ____

3. If derived from rodents, has the material been MAP/RAP/HAP tested? Y/N ____ If yes, attach copy of results

4. I certify that the MAP/RAP/HAP tested materials to be used have not been passed through rodent species outside of the animal facility in question and/or the material is derived from the original MAP tested sample. To the best of my knowledge the material remains uncontaminated with rodent pathogens.

_____ **Initials of Principal Investigator**

M. SPECIAL CONCERNS OR REQUIREMENTS OF THE STUDY: List any special housing, equipment, animal care (i.e., special caging, water, feed, or waste disposal, etc.).

N. PRINCIPAL INVESTIGATOR CERTIFICATIONS: (See Attachment II for further guidance.)

1. I certify that I have attended an approved NIH investigator training course.

   Year of Course Attendance _____ Location _____

2. I certify that I have determined that the research proposed herein is not unnecessarily duplicative of previously reported research.

3. I certify that all individuals working on this proposal are participating in the NIH Animal Exposure Surveillance Program.

4. I certify that the individuals listed in Section A are authorized to conduct procedures involving animals under this proposal, and have, or will receive training in the biology, handling, and care of this species, in aseptic surgical methods and techniques (if necessary), in the concept, availability, and use of research or testing methods that limit the use of animals or minimize distress, in the proper use of anesthetics, analgesics, and tranquilizers (if necessary), and in procedures for reporting animal welfare concerns.

5. **For Column D and Column E Proposals (see Section H):** I certify that I have reviewed the pertinent scientific literature and the sources and or databases and have found no valid alternative to any procedures described herein which may cause more than momentary pain or distress. The methods and sources used in my search are included in the continuation of this Section.

6. I will inform the ACUC of any proposed significant changes in this study.

Principal Investigator Signature: _____ Date: _____

O. CONCURRENCES: **PROPOSAL NUMBER** _____ **(Leave Blank)**

Laboratory/Branch Chief certification of review and approval on the basis of scientific merit.
Scientific Director's signature required for proposals submitted by a Laboratory or Branch Chief.

Name _____ Signature _____ Date _____

Safety Representative certification of review and approval. (Required of all studies utilizing hazardous agents.)

Name _____ Signature _____ Date _____

Facility Manager/Veterinarian certification of resource capability in the indicated facility to support the proposed study.

Facility _____ Name _____ Signature _____ Date _____

Facility _____ Name _____ Signature _____ Date _____

Comments:

Institute Veterinarian certification of review.

Name _____ Signature _____ Date _____

P. FINAL APPROVAL:

Certification of review and approval by the Animal Care and Use Committee Chairperson.

Chairperson _____ Signature _____ Date _____

A ADMINISTRATIVE DATA (continued):

Name: ____________ Degree: ________ Position Title, Affiliation: ____________
○ Fully qualified in all relevant animal procedures ○ Will be trained and supervised by ____________

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D. STUDY OBJECTIVES (continued):

E. RATIONALE FOR USE OF ANIMALS (continued):

F. DESCRIPTION OF EXPERIMENTAL DESIGN AND ANIMAL PROCEDURES (continued):

G. SURVIVAL SURGERY: Surgical Procedures and Aseptic methods (continued):

G. SURVIVAL SURGERY: Multiple survival surgery justification (continued):

H. PAIN OR DISTRESS CATEGORY: Unrelieved pain or distress justification (continued):

N. PRINCIPAL INVESTIGATOR CERTIFICATIONS: Methods and sources used in search (continued):